

COVID-19 At-Home, Point-of-Care (POC) Tests -- as of February 15, 2022											
Test Manufacturer	Test brand name	Date of original FDA EUA	Type of test	Rx or non-Rx test	What sample needs to be collected	Age range for test	Link to most recent FDA EUA letter	Test indication	Test positive percent agreement (sensitivity) and negative percent agreement (specificity) from EUA package insert	Can test be mailed to person's home?	Additional information
Maxim Biomedical, Inc.	MaximBio ClearDetect COVID-19 Antigen Home Test	1/19/22	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/155632/download">www.fda.gov/v/media/155632/download</a>	within 5 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 86.9%. Negative percent agreement 98.9%	unknown	Lateral flow test; result is visually read. Comes in kits of 1, 2, 4, and 25 tests. Results in 15 minutes. Discard used test in household trash. Test can detect the Omicron variant. For tech support, call 301-251-0800 or email tech@maximbio.com. For more info, see www.maximbio.com
Siemens Healthineers	CLINITEST Rapid COVID-19 Antigen Self-Test	12/29/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/155173/download">www.fda.gov/v/media/155173/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 86.5%. Negative percent agreement 99.3%	Can purchase from Amazon	Lateral flow test; result is visually read. Result available in 15 minutes. Test comes in 1-pack and 5-pack. Discard used test materials as household trash. Test will detect Omicron variant. For more info, see www.clinitest.siemens-healthineers.com/us.
SD Biosensor, Inc.	COVID-19 At-Home Test	12/24/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/155123/download">www.fda.gov/v/media/155123/download</a>	within 6 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 95.3%. Negative percent agreement 100%.	unknown	Lateral flow test that is visually read. Comes in kits of 1, 4 and 25 tests. Perform test at room temp (59-86F). Result in 20 min. Discard used materials in household trash. For more info, see https://diagnostics.roche.com/us/en/home.html.
InBios International Inc.	SCoV-2 Ag Detect Rapid Self-Test	11/22/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/154338/download">www.fda.gov/v/media/154338/download</a>	within 5 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 85.7%. Negative percent agreement 100%.	Don't think so	Lateral flow test; result is visually read. Result available in about 25 min. Kits contain 1, 2, 5, or 20 tests. For more info, see www.inbios.com/covid-19 or call 866-462-4671.
iHealth Labs, Inc.	iHealth COVID-19 Antigen Rapid Test	11/5/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/153925/download">www.fda.gov/v/media/153925/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 94.3%. Negative percent agreement 98.1%.	yes	Lateral flow test. Visually read test result. Result available in 15 min. Smartphone app required for test (app available for iPhones or Android). Two tests per package. For more info, see www.ihealthlabs.com. Test can be purchased online.

OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test	6/4/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/149908/download">www.fda.gov/v/media/149908/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 85%. Negative percent agreement 98%.	unknown	Lateral flow test. Visual read. Can download instructions using a smartphone device with QR code reader, but smartphone is not necessary to perform the test. Result available in 30 min. Comes as a package with 2 tests. For more info, go to <a href="http://www.inteliswa.com">www.inteliswa.com</a> .
Detect, Inc.	Detect Covid-19 Test	10/28/21	single molecular test or serial molecular testing	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/153663/download">www.fda.gov/v/media/153663/download</a>	Can use in individuals suspected of having COVID-19 (single molecular testing). Can also be used for serial molecular testing to screen people without symptoms or other epi reason(s) to suspect COVID-19.	Positive percent agreement 90.9%. Negative percent agreement 97.5%.	uncertain, but appears to be yes	Is a Reverse Transcription Loop-mediated Isothermal Amplification (LAMP) test. Result in one hour. Test result read visually from reader device. Smartphone with free downloadable "Detect App" is required to perform test. Two tests per package. For more info, see <a href="http://www.detect.com">www.detect.com</a> . 24/7 customer support at 855-322-3692 or <a href="mailto:support@detect.com">support@detect.com</a>
Celltrion USA, Inc.	Celltrion DiaTrust COVID-19 Ag Home Test	10/21/21	single antigen test or serial antigen tests	non-Rx	mid nasal turbinate swab	age ≥ 14	<a href="https://www.fda.gov/v/media/153418/download">www.fda.gov/v/media/153418/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 86.7%. Negative percent agreement 99.8%.	unknown	Lateral flow test. Visual read. Smartphone needed to download app which provides instructions. Result read after 15 minutes. For more info see <a href="http://www.diatrusted.com">www.diatrusted.com</a> . Kits comes in packages of 1 test, 2 tests, 5 tests, and 25 tests.
ACON Laboratories, Inc.	Flowflex COVID-19 Antigen Home Test	10/4/21	single antigen test	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/152700/download">www.fda.gov/v/media/152700/download</a>	within 7 days of symptom onset or without symptoms or other epi reasons to suspect COVID-19	Positive percent agreement 93%. Negative percent agreement 100%.	unknown	Lateral flow test. Visual read, does not require a reader device or smartphone. Result read after 15 minutes. For more info see <a href="http://www.aconlabs.com">www.aconlabs.com</a> . Customer service = 800-838-9502.
Becton Dickinson and Company (BD)	BD Veritor At-Home COVID-19 Test	8/24/21	single antigen test or serial antigen tests	non-Rx	anterior nasal swab	age ≥ 2	<a href="https://www.fda.gov/v/media/151771/download">www.fda.gov/v/media/151771/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 84.6%. Negative percent agreement 99.8%	unknown	A lateral flow test. Requires smartphone, internet connection, and app to do test. Results available in 20 minutes. More test info available at <a href="http://www.bdveritorathome.com">www.bdveritorathome.com</a> . More labeling info available at <a href="http://www.bd.com/e-labeling">www.bd.com/e-labeling</a> .
Access Bio, Inc.	CareStart COVID-19 Antigen Home Test	8/2/21	single antigen test or serial antigen tests	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/v/media/151245/download">www.fda.gov/v/media/151245/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 87%. Negative percent agreement 98%.	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results must be read between 10-15 minutes after test started. According to the package labeling, a smartphone is needed; however, the FDA EUA letter states a smartphone can be used, but is not required. For more information, see <a href="https://accessbiodiagnostics.net">https://accessbiodiagnostics.net</a>

OraSure Technologies, Inc.	InteliSwab COVID-19 Rapid Test Rx	6/4/21	single antigen test	Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/149904/download">www.fda.gov/media/149904/download</a>	within first 7 days of symptom onset	Positive percent agreement 85%. Negative percent agreement 98%.	unknown	Specimen collection not observed. A lateral flow test. No analyzer device needed. Results in 30 minutes. For more info, see <a href="https://www.intelismwab.com">www.intelismwab.com</a> .
Lucira Health Inc.	Lucira CHECK-IT COVID-19 Test Kit	4/9/21	single molecular test	non-Rx	anterior nasal turbinate swab	age ≥ 2	<a href="https://www.fda.gov/media/147492/download">www.fda.gov/media/147492/download</a>	with or without COVID-19 symptoms or epi reason to suspect COVID-19	Positive percent agreement 92%. Negative percent agreement 98%.	yes	For more information about test or to order, see <a href="https://www.lucirahealth.com">www.lucirahealth.com</a> . Smartphone or smart device not needed for test. Result available between 11 and 30 minutes.
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID-19 Antigen Self Test	4/1/21	single antigen test or serial antigen tests	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/147251/download">www.fda.gov/media/147251/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 84.6%. Negative percent agreement 98.5%.	yes	For more information, see <a href="https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html">www.abbott.com/BinaxNOW-Test-NAVICA-App.html</a> . Test available at CVS, Walmart, and other stores or online. Result available in 15 minutes.
Quidel Corp.	QuickVue At-Home OTC COVID-19 Test	3/31/21	single antigen test or serial antigen tests	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/147247/download">www.fda.gov/media/147247/download</a>	within 6 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 83.5%. Negative percent agreement 99.2%.	unknown	Lateral flow test; result is visually read. For more information, see <a href="https://quickvueathome.com/">https://quickvueathome.com/</a> . Result in 10 minutes. Dispose of materials in household trash.
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID-19 Ag Card 2 Home Test	3/31/21	serial antigen testing	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/147256/download">www.fda.gov/media/147256/download</a>	with or without COVID-19 symptoms or epi reason to suspect COVID-19	Positive percent agreement 84.6%. Negative percent agreement 98.5%.	unknown	Lateral flow test; result visually read. Unclear if test currently available. Test uses telehealth proctor. Must have a smart device or computer. Result available in 15 minutes.
Cue Health Inc.	Cue COVID-19 Test for Home and Over the Counter (OTC) Use	3/5/21	single molecular test	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/146467/download">www.fda.gov/media/146467/download</a>	with or without COVID-19 symptoms or epi reason to suspect COVID-19	Positive percent agreement 97.4%. Negative percent agreement 99.1%.	unknown	For more information, see <a href="https://www.cuehealth.com/what-is-cue/how-cue-detects-COVID-19">https://www.cuehealth.com/what-is-cue/how-cue-detects-COVID-19</a> . Smartphone needed to download app and use test. See list of compatible smartphones at <a href="https://www.cuehealth.com">www.cuehealth.com</a> . Result in about 20 min.
Quidel Corp.	QuickVue At-Home COVID-19 Test	3/1/21	single antigen test	Rx	anterior nares swab	age ≥ 8	<a href="https://www.fda.gov/media/146309/download">www.fda.gov/media/146309/download</a>	within first 6 days after symptom onset	Positive percent agreement 84.8%. Negative percent agreement 99.1%.	unknown	Lateral flow test; result is visually read. Unclear if test currently available. Result in 10 minutes. For help with test, call 833-QUICKVUE (833-784-2588). For detailed instructions online, go to <a href="https://www.quickvueathome.com">www.quickvueathome.com</a> .
Abbott Diagnostics Scarborough Inc.	BinaxNOW COVID-19 Ag Card Home Test	12/16/20	single antigen test or serial antigen tests	non-Rx	anterior nares swab	age ≥ 2	<a href="https://www.fda.gov/media/144576/download">www.fda.gov/media/144576/download</a>	within 7 days of symptom onset (single antigen test) or without symptoms or other epi reasons to suspect COVID-19 (serial antigen testing)	Positive percent agreement 84%. Negative percent agreement 98.3%.	yes	Lateral flow test; result visually read. For more information, see <a href="https://www.abbott.com/BinaxNOW-Test-NAVICA-App.html">www.abbott.com/BinaxNOW-Test-NAVICA-App.html</a> . Available through <a href="https://www.emed.com">www.emed.com</a> . Uses telehealth proctor. Smart device or computer needed. Result in 15 minutes.

Ellume Limited	Ellume COVID-19 Home Test	12/15/20	single antigen test	non-Rx	mid nasal turbinate swab	age ≥ 2	<a href="https://www.fda.gov/media/144457/download">www.fda.gov/media/144457/download</a>	With or without COVID-19 symptoms or epi reason to suspect COVID-19. EUA letter does not specify a specific number of days that a symptomatic person must be tested by.	Positive percent agreement 95%. Negative percent agreement 97%.	yes	Lateral flow test; result read by an instrument. For more info, see <a href="https://www.ellumecovidtest.com">www.ellumecovidtest.com</a> . Result in 15 minutes. Smartphone and app required as part of test. Customer service number is 888-885-6121.
Lucira Health Inc.	Lucira COVID-19 All-In-One Test Kit	11/17/20	single molecular test	Rx	anterior nasal turbinate swab	age ≥ 14	<a href="https://www.fda.gov/media/143810/download">www.fda.gov/media/143810/download</a>	individuals suspected of having COVID-19 by healthcare provider	Positive percent agreement 94.1%. Negative percent agreement 98%.	no	For more information, see <a href="https://shop.lucirahealth.com/">https://shop.lucirahealth.com/</a> . Result available between 11 and 30 minutes.